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Has collaborative commercialization arrived in India?

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Faced with many uncertainties after the introduction of a series of reforms from the 1990s, both Indian and foreign firms have closely followed the growth of the pharmaceutical industry. Looking at modest health reforms, a large untapped market coupled with increased spending on healthcare and a subtle change in disease patterns, business leaders, policy makers and consumers have evinced keen interest at the emerging Indian market potential.

The Indian pharmaceutical industry has had its share of significant policy changes that reflect its growth trajectory. With the introduction of only process patents in the 70s, India had over a period of time developed enviable manufacturing and distribution strengths with lower operational costs. There has been much excitement about the change to a product patent regime with an anticipation of multinational firms eyeing Indian firms for not just their manufacturing capabilities but also their R&D capabilities for improved product life cycle management. This would mean an increase in collaborative partnerships. However, is this really happening?

Indian firms face multiple challenges, including the element of newness to proprietary R&D, prohibitive costs to bring a drug into the market and negotiating regulatory checkpoints along the way. To most, this vertical integration of R&D is economically unrealistic. However, a few firms such as Connexios Life Sciences (Bangalore) and Glenmark Pharmaceuticals (Mumbai) have focused on proprietary R&D and not on contract research. Similarly Piramal Life Sciences (Mumbai) had augmented their pipeline with research deals with Merck and Eli Lily.

However, the predominant strength and focus has been downstream capabilities. The hope with the patent changes was an increased focus on building indigenous R&D capability while answering multinational concerns. While patenting by Indian firms has per se increased, it is worth noting that the number of product patent filings vis-a-vis foreign firms has not drastically changed (848 by MNCs to 28 by Indian firms from 2005-2009).

From the point of view of multinationals, the new patent regime has promised patent protection but these firms face both a severe challenge in downstream capabilities that are critical to reach far and wide and from generics that pose a serious threat of erosion of sales revenues. Given the growing market opportunity in India, reachability of affordable drugs would be a key business driver.

Furthermore, it is clear that the mandate of the government is to provide affordable medicines to the greater public. Starting with the compulsory licensing of Bayer's Nexavar to NatcoPharma Limited at a fraction of the original price, there seems to be interest in providing 'access' to drugs. This has proved conducive to collaborative ventures which rely on integrated global organization and effective collaboration.
Firms such as Strides Arcolab, Emcure Pharmaceuticals and MSD Pharmaceuticals have inked either technology or marketing deals with Gilead, Roche and Merck respectively. Bayer and Cadila Healthcare plan to enter into a licensing agreement as well, as reported in Indian media.

So would we be seeing more of a new 'collaborative commercialization'?
Yes, the number of collaborations has increased and has been strong business drivers and do show promising signs of further increase. The nature of these collaborations would be interesting. These collaborations tend to be more towards manufacturing and marketing deals between multinationals and Indian firms.

Given the triumvirate of product patent changes, challenges for Indian firms to switch to drug discovery and precious downstream capabilities, we would expect to see more multinational- domestic tie-ups for voluntary licensing deals where the multinational technology know-how is transferred for efficient manufacturing and extensive marketing by Indian firms. This would work in two ways - one the Indian firms who have not yet set sight on R&D can still utilize their manufacturing and marketing capability for new drugs to enter the market and two- multinational firms do not need to grapple with the fear of compulsory licensing which could remove their patent protection early on.

It would be of interest to see what the patent changes in India means as far as collaborations and licensing goes. India presents a conundrum with an untapped market for diseases such as HIV/AIDS, diabetes, heart disease and so on with most of the population unable to afford costly medications. These collaborations might mean a working solution to both multinational and domestic pharmaceutical firm growth drivers by building bridges to create a sustainable business model.